

ORIGINAL ARTICLE

Analysis of Risk Factors of Stoma Related Complications: An Observational Study

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ABSTRACT

Background: Stoma surgery involves the creation of an abdominal opening to divert feces or urine, commonly through colostomy or ileostomy. While often lifesaving, stoma formation can lead to several complications, affecting the patient's physical, psychological, social, and financial well-being. Common complications include parastomal hernia, prolapse, retraction, and infection. Identifying risk factors associated with these complications is essential for improving outcomes.

Aim: To study the stoma related complication, risk factors assessment which will include patient related factors and intraoperative factors and to see if any modifiable factors are seen with regards to these that could help change the patient outcomes.

OBJECTIVE

1. To determine the incidence and prevalence of stoma-related complications
 - Identify the frequency of early (≤ 30 days) and late (> 30 days) complications in stoma patients.
2. To classify and analyze the types of complications
 - Assess common complications such as ischemia, leakage, retraction, prolapse, parastomal hernia, stenosis, and peristomal skin irritation.
3. To identify risk factors associated with complications

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- Investigate patient-related factors (e.g., age, comorbidities, nutritional status).
 - Assess surgical factors (e.g., emergency vs. elective surgery, stoma site selection, technique).
4. To evaluate the impact of complications on clinical outcomes
 - Analyze hospital readmissions, reoperations, and prolonged hospital stays due to stoma-related issues.

KEYWORDS

- Stoma • Colostomy • Ileostomy • Parastomal Hernia • Complications
- Risk Factors • Observational Study • MKCG Medical College.

INTRODUCTION

It has been estimated that around 100,000 people in the United States alone undergo surgeries that result in a stoma each year.¹

The most common underlying conditions resulting in stoma formation as per literature are colorectal cancer, bladder cancer, ulcerative colitis, Crohn's disease and Trauma surgeries. An array of stoma related complications can occur following the formation of stoma and hence the procedure of stoma creation is highly morbid. These could be early complications like stomal congestion, gangrene, retraction, parastomal abscess, peristomal irritation seen in the immediate Post-operative period or late complications like stomal prolapse, stomal stenosis and parastomal hernia. The reported incidence of these conditions varies widely in the literature. Most of the data and study done on stomas put the overall rate of complications as high as 21%-70%. The individual rates of the complications also vary with different studies. The different complications may occur as early or as late complications. Many factors can predispose to these complications which include patient factors like obesity, underlying disease (indication), age and intraoperative factors like surgeons' expertise, type of approach (laparoscopic or open), placement of bridge. Other factors such as pre-operative stoma site marking can be used for improving patients' Post-operative quality of life, promoting patient independence, and decreasing the rates of post-operative complications.

This paradox highlights the importance and tremendous impact of the surgeon's role in dealing with ostomies. The surgeon must be proficient at not only creating the stoma but also handling post-operative complications.

The study is being designed to look at the types of stoma, the related complications, the setting of the surgery and the clinical outcomes of the patients in terms of the varying complications among those who have undergone the surgery in our unit and to look at modifiable risk and outcomes from the data that has been collected.

MATERIALS AND METHODS

Study Setting:

This study was conducted in the Department of General Surgery, M.K.C.G. Medical College and Hospital, Berhampur.

Study Design:

The study was conducted as a retrospective and prospective analysis of all the patients undergoing stoma surgeries (colostomy and ileostomy) in the Department of General Surgery during the period ranging from March 2023 to February 2025. This included the retrospective analysis of all the discharge summaries, operation notes, and outpatient charts of all the patients included in this study.

All patients who underwent stoma surgery in this unit during the above-mentioned period for any reason, emergency or elective were included in the study.

Inclusion Criteria:

1. Patients with a Stoma
 - Individuals who have undergone a colostomy or ileostomy.
 - Patients with either temporary or permanent stomas.
2. Age Criteria
 - Adults ≥ 18 years.

3. Time Since Surgery

- Patients who have had a stoma for a minimum of 1 month (for early complications assessment).
- Patients who have had a stoma for at least 6 months (for late complications assessment).

4. Type of Surgery

Patients who underwent stoma formation due to:

- Colorectal cancer
- Inflammatory bowel disease (IBD)
- Trauma
- Other surgical conditions requiring stoma formation

5. Follow-Up Availability

- Patients willing to participate in follow-up visits for complications assessment.

6. Ability to Provide Consent

- Patients who can provide informed consent.

7. Access to Medical Records

- Patients whose medical records contain sufficient data on stoma formation, post-operative complications, and follow-up.

Exclusion Criteria:

1. Patients Without a Stoma
2. Insufficient Medical Records (for Retrospective Study)
3. Severe Comorbidities Affecting Outcomes
 - Patients with terminal illnesses (e.g., advanced malignancy under palliative care) where stoma-related complications are not the primary concern.
 - Patients with severe organ failure (e.g., end-stage heart failure, liver failure) that could confound study outcomes.
4. Lost to Follow-Up or Non-Compliance (for Prospective Study)
 - Patients who are unwilling or unable to complete follow-up visits or quality-of-life assessments.
 - Patients unable to provide informed consent, with no legal representative available.

5. Pediatric Patients

- Individuals younger than 18 years.

6. Stoma Reversal Before Data Collection.

Participant Selection:

All inpatients admitted and has undergone stoma (either colostomy or ileostomy) surgery from the year March 2023 to February 2025 in the department of General Surgery in M.K.C.G. Medical College & Hospital, Berhampur.

Sample size:

All inpatients admitted who has undergone stoma surgery from the March 2023 to February 2025 in the Department of General Surgery, M.K.C.G. Medical College & Hospital, Berhampur were considered.

A Total of 214 patients were identified during this period as having being in the required study group. Out of this population 43 patients were found to have complications related to stoma surgery which were within the parameters of the study.

Variables considered in the study:

- **Patient factors** – age, gender, comorbidities, indication for surgery, obesity, albumin and hemoglobin
- **Operative factors** - elective/emergency setting, loop vs end stoma, type of stoma, laparoscopic / open approach
 - Post-operative complications – stomal gangrene, stoma retraction, mucocutaneous separation, parastomal abscess, stomal prolapse, parastomal hernia and stomal stenosis. These complications being classified into early and late complications.

METHODS

This observational study was conducted in the Department of General Surgery, MKCG Medical College and Hospital, Berhampur, from March 2023 to February 2025. A total of 214 patients who underwent stoma formation (colostomy or ileostomy) were included. Data were collected retrospectively and prospectively, including patient demographics, surgical details, laboratory parameters, and complications.¹ Complications were categorized as early (≤ 30 days) or late (> 30 days).² Statistical analysis was performed to determine associations between various factors and stoma related complications.³

RESULTS

Of the 214 patients, 43 (20.1%) developed stoma-related complications.⁴ The most common complication was parastomal hernia (48.84%), followed by retraction/stricture (16.28%) and mucocutaneous separation (13.95%).⁵ No statistically significant association was found between complications and variables such as age, gender, type of surgery (elective vs. emergency), comorbidities, albumin level, hemoglobin level, BMI, type of stoma (colostomy vs. ileostomy, end vs. loop), or surgeon experience.⁶ Further analysis comparing early and late complications also showed no significant correlation with these variables.⁷ Conclusion: The overall complication rate was 20.1%, with parastomal hernia being the most common. None of the analyzed patient or surgical factors showed a statistically significant association with complications.⁸ Further prospective studies with larger sample sizes and broader inclusion criteria are recommended to better assess risk factors and improve stoma care outcomes. The break-down of number of different complications seen in the patients analyzed are given in the table below.

Table 1: Break-down of complications seen in the study population

Complication	No. of Cases	Percentage
Abscess	1	2.33
Gangrene	2	4.65
Mucocutaneous separation	6	13.95
Retraction/Stricture	7	16.28
Stomal prolapse	6	13.95
Parastomal hernia	21	48.84
Total	43	100.00

The different variables compared in the study and the results obtained after analyzing the data are given below.

Age Distribution

Table 2: Age distribution of entire study population vs complication

Parameter		Complications		p-value
		Yes	No	
Age in Years	≥60	36 (20.5%)	140 (79.5%)	0.777
	< 60	7 (18.4%)	31 (81.6%)	

Age did not show any statistically significant association to stoma

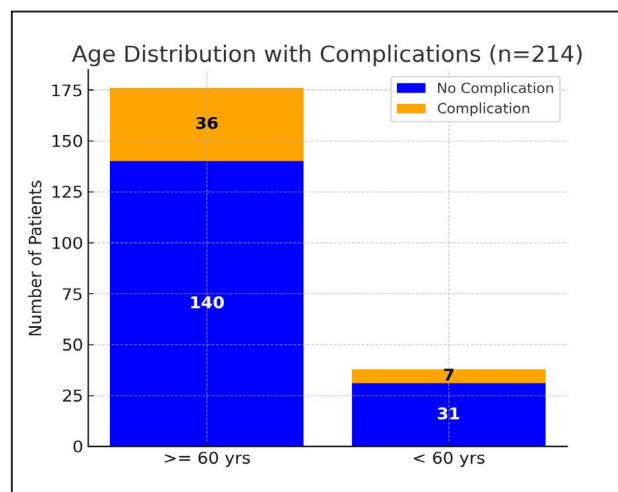


Figure 1: Age Distribution compared to complications

Table 3: Distribution of Gender of Population vs Complications

Parameter		Complications		p-value
		Yes	No	
Gender	Male	25 (17.2%)	120 (82.2%)	0.131
	Female	18 (26.1%)	51 (73.9%)	

Table 3 Gender distribution of population vs complication
Gender did not show any statistically significant association to stoma complications (p-value=0.131)

Gender Distribution

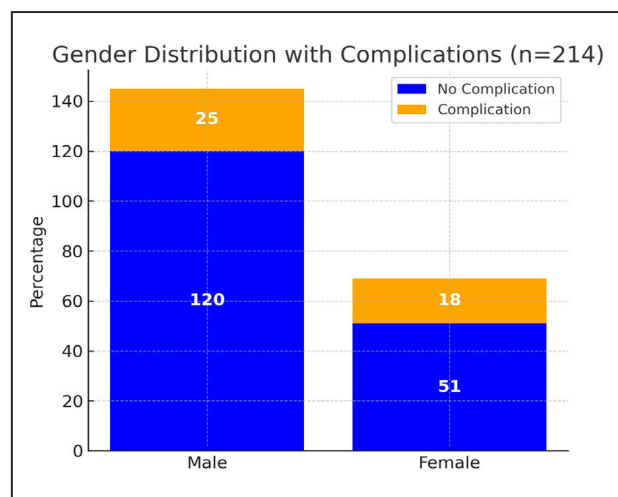


Figure 16. Gender Distribution compared to complications

Initial Diagnosis

Table 4: Initial Diagnosis vs Complication

Parameter		Complications		p-value
		Yes	No	
Initial	Malignancy	18 (21.2%)	67 (78.8%)	0.748
Diagnosis	Non Malignancy	25 (19.4%)	104 (80.6%)	

Initial diagnosis of malignancy did not show any statistically significant association to stoma complications (p-value= 0.748).

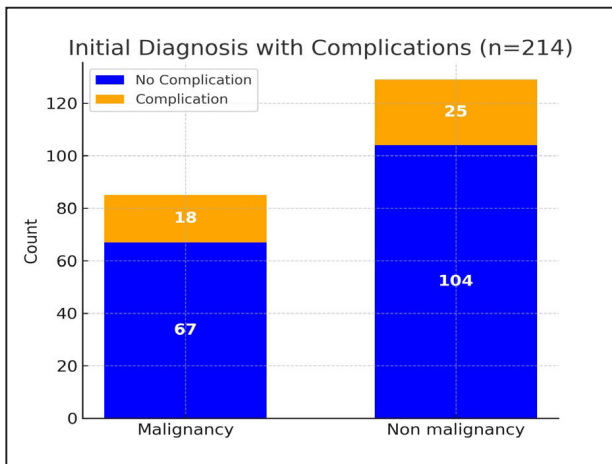


Figure 17: Initial diagnosis compared with complications

Emergency vs Elective

Table 5: Type of surgery in total population Setting of surgery (elective/emergency) did not show any statistically significant association to stoma complications (p-value= 0.259)

Parameter		Complications		p-value
		Yes	No	
Type of surgery	Elective	16 (16.7%)	80 (83.3%)	0.259
	Emergency	27 (22.9%)	91 (77.1%)	

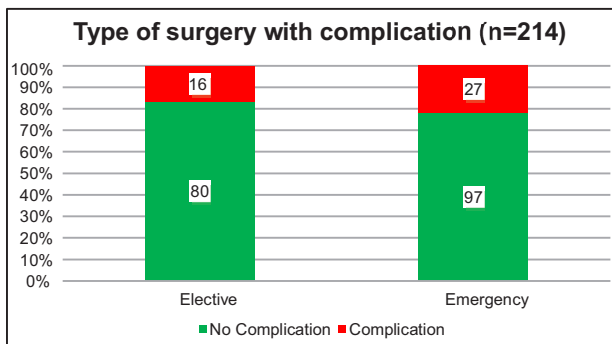


Figure 18. Type of surgery compared with complication

Person Operating

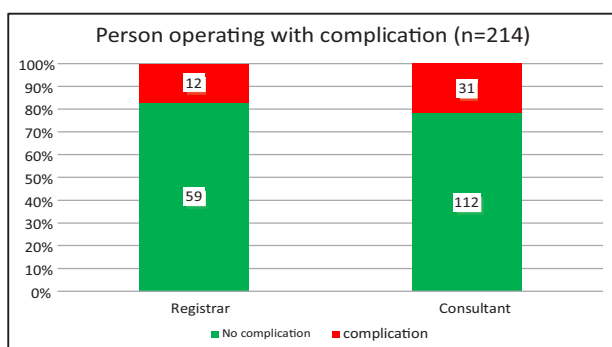


Figure 19: Comparison of person operating Compared with complications

Table 6: Person operating compared with the total population Person operating on the patient did not show any statistically significant association to stoma complications (p-value= 0.412)

Parameter		Complications		p-value
		Yes	No	
Person Operating	Registrar	12 (16.9%)	59 (83.1%)	0.412
	Consultant	31 (21.7%)	112 (78.3%)	

Comorbidities

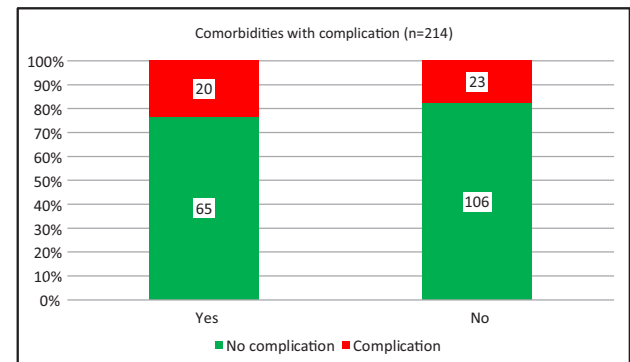


Figure 20. Presence of comorbidity compared with complication

Table 7: Comorbidities compared to total population

Parameter		Complications		p-value
		Yes	No	
Presence of comorbidities	Yes	20 (23.5%)	65 (76.5%)	0.309
	No	23 (17.8%)	106 (82.2%)	

Presence of comorbidity did not show any statistically significant association to stoma complications (p-value= 0.309)

Albumin

The normal value of albumin is taken as 3.5-5.4g/dL

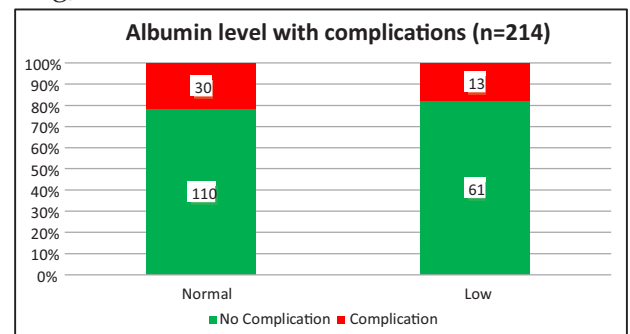


Figure 21. Albumin level in patient compared to complications

Table 8: Albumin values compared to the total population

Parameter		Complications		p-value
		Yes	No	
Albumin Levels	Normal	30 (21.4%)	110 (78.6%)	0.309
	Low	13 (17.6%)	61 (82.4%)	

Albumin level did not show any statistically significant association to stoma complications (p-value= 0.503)

Hemoglobin

The normal value of hemoglobin is taken as 12-15g/dL in females and 13-16g/dL in males

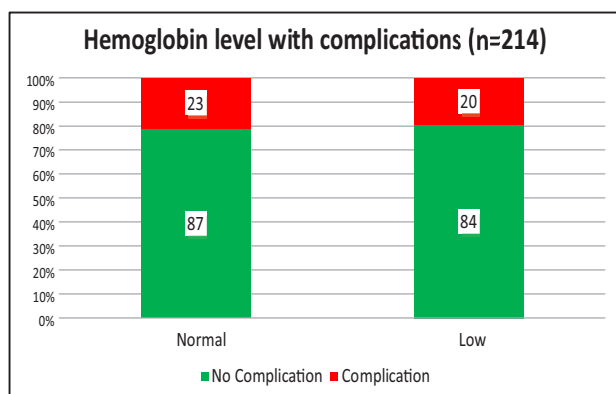


Figure 22. Hemoglobin Level in patients compared to complications

Table 9: Hemoglobin level compared to the total population

Parameter		Complications		p-value
		Yes	No	
Hemoglobin Levels	Normal	23 (20.9%)	87 (79.1%)	0.759
	Low	20 (19.2%)	84 (80.8%)	

Hemoglobin level did not show any statistically significant association to stoma complications (p-value= 0.759)

Colostomy/Ileostomy

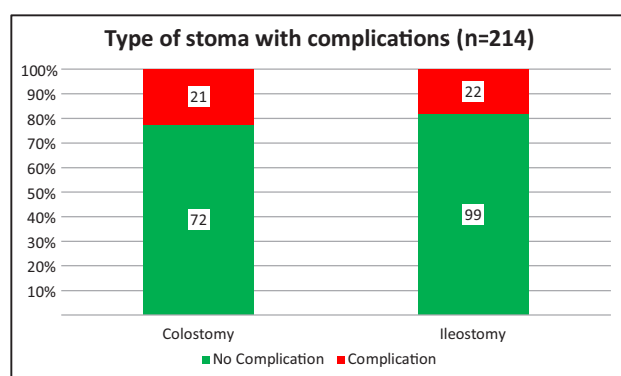


Figure 23. Comparing colostomy/ileostomy compared with complication

Table 10: Colostomy/Ileostomy Compared With Complication

Parameter		Complications		p-value
		Yes	No	
Type of Stoma	Colostomy	21 (22.6%)	72 (77.4%)	0.106
	Ileostomy	22 (18.2%)	99 (81.8%)	

Type of stoma (colostomy/ileostomy) did not show any statistically significant association to stoma complications (p-value= 0.106)

End and Loop Stoma

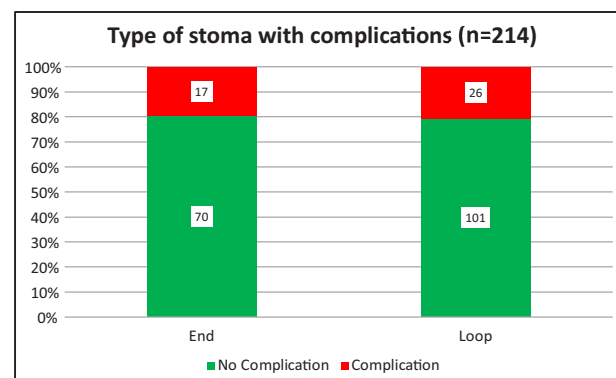


Figure 24: Comparison of End and loop stoma with complications

Table 11: End/ loop stoma with complication in total population
Type of stoma (end/loop) did not show any statistically significant association to stoma complications (p-value= 0.867)

Parameter		Complications		p-value
		Yes	No	
Type of Stoma	End	17 (19.5%)	70 (80.5%)	0.867
	Loop	26 (20.5%)	101 (79.5%)	

BMI

The normal value of BMI is in the range 18.5-24.9kg/m². Below 18.5 is low and above 24.9 is high.

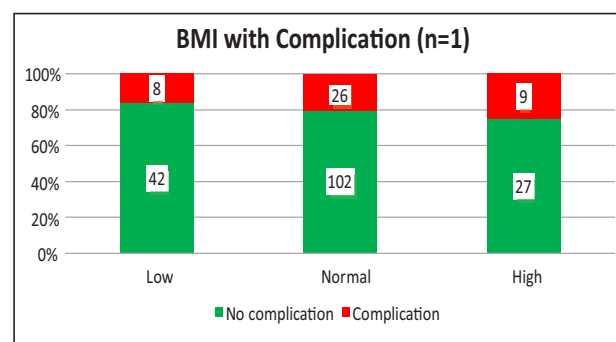


Figure 25: BMI compared with complication

Table 12: BMI distribution with complication in total population
BMI did not show any statistically significant association to stoma complications (p-value= 0.587)

Parameter		Complications		p-value
		Yes	No	
BMI	Low	8 (16.0%)	42 (84.0%)	0.587
	Normal	26 (20.3%)	102 (79.7%)	
	High	9 (25.0%)	27 (75.0%)	

As seen from the values given above, none of the factors analyzed in this study showed any significant bearing with regard to causing complications in patients undergoing stoma surgeries.

Another comparison done was comparing the various variables considered with early and late complications among the patients who had developed complications (n=43). The comparison was done to see if there was any impact of these variables with respect to the early and late complications in stoma surgery.

Given below is a comparison of the different parameters with regard to early and late complications.

Table 13: comparing the various factors with early and late complications (N=43)

	Complications (n=43)		p-value
Parameters	Early Complications	Late Complications	
<i>Age in Years</i>			
≥60	4 (57.1%)	3 (42.9%)	.177
<60	11 (30.6%)	25 (69.4%)	
<i>Gender</i>			
Male	8 (30.8%)	18 (69.2%)	.484
Female	7 (41.2%)	10 (58.8%)	
<i>Initial diagnosis</i>			
Malignancy	5 (33.3%)	10 (66.7%)	.876
Non malignancy	10 (35.7%)	18 (64.3%)	
<i>Setting of surgery</i>			
Elective	4 (25%)	12 (75%)	.141
Emergency	10 (37%)	17 (63%)	
<i>Person operating</i>			
Registrar	5 (36.4%)	7 (63.6%)	.905
Consultant	10 (34.4%)	21 (65.6%)	
<i>Comorbidities</i>			
Yes	4 (20.0%)	16 (80.0%)	.056
No	11 (47.8%)	12 (52.2%)	
<i>Albumin</i>			
Low	5 (38.5%)	8 (61.5%)	.189
Normal	14 (46.7%)	16 (53.3%)	
<i>Hemoglobin</i>			
Low	12 (60%)	8 (40%)	.052
Normal	11 (47.8%)	12 (52.2%)	
<i>Type of Stoma (anatomy)</i>			
Colostomy	6 (28.6%)	15 (71.4%)	.396
Ileostomy	9 (40.9%)	13 (59.1%)	
<i>Type of stoma (surgical)</i>			
End	5 (26.7%)	12 (73.3%)	.408
Loop	10 (39.3%)	16 (60.7%)	
<i>BMI</i>			
Low	5 (62.5%)	3 (37.5.0%)	.054
Normal	6 (23.1%)	20 (76.9%)	
High	6 (66.7%)	3 (33.3%)	

When the data of the factors were analyzed with early and late complications, there was no significant correlations.

DISCUSSION

In the study conducted, the overall percentage of complications was noted to be 20.1%. Most of the data and study done on stomas put the overall rate of complications as high as 21%-70% (14, 26). This is probably due to the fact that most studies done also took skin complications and high stoma output also into consideration as a complication, which was not done in this particular study.

On the analysis of the individual variables with the complications the results seen were as follows.

Age

As done in most studies quoted here, the cut off age was taken as 60yrs for the purpose of analysis (14, 20, 26). In our study 176 patients were in the age group of ≥ 60 yrs, comprising 82.2% of the study population. The though in the previous studies it was seen that an age of >60 years was a risk factor for the development of complications, in our study conducted, age did not appear to be an factor associated with causing any complications.

Gender

There were 145 male patients 69 female patients in the sample collected for this study. There were no significant references with regard to the Gender being a factor leading to stoma complications. Our study also did not show age as a factor in causing stoma complications.

Initial Diagnosis

Initial diagnosis prior to the surgery was not a conclusive factor causing complications. Among the study sample 85 patients had malignancy as the initial diagnosis comprising 39.7% of the sample population (n=214). According to some studies (33,70) malignancy had a higher chance of causing stoma complications while in others non-malignant causes such as Crohn's disease was found to have a greater risk of developing complications. The study conducted by us did not show any bearing of malignancy being a factor.

Emergency/ Elective surgery

The setting of surgery, i.e. elective or emergency was found to have a bearing in stoma complications. In some studies, conducted showed a better outcome of surgery as well as lesser complications in patients operated in an elective setting as opposed to emergency setting (5, 13 19). There was 96 elective surgeries and 118 emergency surgeries done in the sample, constituting 44.9% and 55.1% respectively. Our study did not show any statistical difference in outcome.

Person Operating

In 2 publications referenced for this study, it was noted that patients operated by colorectal surgeons had better outcomes as compared to those done by general surgeons (19, 30). In our study, we considered the possibility of the same but comparison was done between registrars and consultants. During the study period, 71 surgeries were performed by registrars and 143 surgeries by consultants. The final analysis did not show any significance.

Comorbidities

The presence of certain comorbidities such as diabetes, immunocompromised states have been seen as a factor responsible in causing complications following stoma surgery. In this study, the presence of any comorbidity was considered and not individual comorbidities. 85 patients (39.7%) of the sample population had 1 or more comorbidities which also included TB. The study did not see any significant difference in complications comparing patients with comorbidities and patients without comorbidities.

Albumin

There was no study seen studying albumin as a factor. This was hence selected as a probable factor that could alter the outcome of stoma surgery. The cut off taken for normal range of albumin was 3.5- 5.4g/dL. 74 patients (35.6%) of the study population was seen to have low albumin level. The analysis of the data however did not show low albumin as a cause for stoma complications.

Hemoglobin

Low hemoglobin was also taken as a factor that could potentially be a cause for complication in stoma. No data was seen available on this factor either. The cut off

considered for the same was 12g/ dL for females and 13g/dL in males as per internationally recognized cut offs. 104 patients (48.6%) of the study population were found to have a low hemoglobin. The study done by us however did not show low hemoglobin to be a factor causing stoma complications.

Colostomy Vs Ileostomy

Though there are inherent differences in the surgical techniques and the fact that the 2 surgeries are done for different reasons, a comparison was done to see if there was any difference in the rate of complications following the surgery. Most studies done does not show any difference in the outcomes of the 2 surgery (5, 6, 7, 18, 20).

There was 93 colostomy and 121 ileostomies done in the study population contributing 43.5% and 56.5% of the population respectively. Though there was a slight percentage increase in complications shown among patients with colostomy, this was not statistically significant as the p-value was 0.106

End Vs Loop Stoma

As with the previous factor considered, the techniques and reasons for doing the 2 surgeries are different. There were no particular studies seen comparing loop stoma with end stoma (as most studies mentioned in the bibliography look at colostomy as end and ileostomy as loop). In our study population we had 87 end stoma and 127 loop stomas. This also includes a few loop colostomies.

The analysis of the data however does not show any statistically significant differences in complication comparing these 2 types of stomas. The p-value calculated was 0.867.

BMI

BMI (especially high BMI) is considered a predisposing factor leading to stoma complications (3, 7, 11, 13, 14, 26, 27, 35). The normal value for BMI is in the range of 18.5 to 24.9 kg/m² (both values inclusive) as per internationally accepted norms. Any value below this range is low and above the range is considered high respectively. In the study population here the distribution of BMI was - 50 (23.4%) low, 128 (59.8%) normal and 36 (16.8%) high respectively.

In our study even though there was an increase in the percentage of patient with

high BMI with complication, as the P value calculated for the same was 0.587, it was found to be insignificant.

Comparing the various factors with early and late complications.

The data of the 43 patients with complications were further analyzed. Their factors were checked against early and late complications. The values are as given in (Table 13).

The data analyzed did not show any significant findings relating the factors with early and late complications when the P values were assessed.

CONCLUSION

1. The overall complication rate in this study was 20.1%, which is slightly lower than those reported in other studies. This may be attributed to the exclusion of skin-related complications and high stoma output from our analysis.
2. In our retrospective study, we examined multiple factors associated with stoma-related complications. While certain factors such as malignancy, emergency procedures, obesity, and low albumin levels appeared to have a higher incidence of complications, none of these associations were statistically significant.
3. A considerable proportion of our patients (nearly one-fourth) had undergone their initial surgery at external institutions and were referred to our center for stoma-related complications or reversal. This external patient cohort may have influenced our findings. Future studies focusing exclusively on patients treated at our center may yield more definitive correlations.
4. The classification of complications into early and late phases did not reveal any statistically significant associations with the studied risk factors. Consequently, our retrospective study did not establish any definitive correlation between the analyzed factors and stoma-related complications.
5. We recommend a prospective study with a larger sample size that includes skin-related complications and other relevant factors to better evaluate potential associations.

ETHICAL CONSIDERATIONS

Ethical standards were rigorously upheld throughout the study to ensure the protection of the participants' rights and well-being. The study protocol was reviewed and approved by the Institutional Ethics Committee of MKCG Medical College and Hospital prior to initiation. Informed consent was obtained from all patients after a comprehensive explanation of the study objectives, procedures, potential risks, and anticipated benefits. Each participant was provided with a detailed information sheet in their native language, and ample time was given for them to ask questions before consenting to participate. To ensure confidentiality, each patient was assigned a unique identification number, and all data were stored in a secure database with restricted access. The identity of the participants was never disclosed in any reports or publications. Furthermore, the study was conducted in strict accordance with the ethical guidelines established by the Indian Council of Medical Research (ICMR) and the Declaration of Helsinki. Any adverse events or complications that arose during the study were promptly addressed by the clinical team, and necessary medical care was provided without delay. The ethical considerations extended to ensuring that the study procedures did not interfere with the standard clinical care of the patients, and every effort was made to minimize discomfort or risk during both diagnostic and surgical interventions. The commitment to ethical practices was a cornerstone of the research process and underscored the team's responsibility to maintain the highest standards of clinical care and scientific integrity.

Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper. The study was conducted independently without any financial or personal relationships that could have influenced its outcome.

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